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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,863	07/13/2005	Youe-Kong Shue	5176-14PUS	4452

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COHEN, PONTANI, LIEBERMAN & PAVANE
551 FIFTH AVENUE
SUITE 1210
NEW YORK, NY 10176

EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

MAIL DATE	DELIVERY MODE
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11/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,863	Applicant(s) SHUE ET AL.	
	Examiner Irene Marx	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 17-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The application should be reviewed for errors.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

Applicant's election without traverse electing to prosecute the invention of Group I, claims 1-16 on 10/1/07 is acknowledged.

Claims 1-16 are being considered on the merits. Claims 17-26 are withdrawn from consideration as directed to a non-elected invention. Claims 17-26 are indicated as cancelled. Yet no formal amendment is of record canceling these claims.

Note that in accordance with 37 CFR 1.121:

(1) *Claim listing.* All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of "canceled" or "not entered" may be aggregated into one statement (*e.g.*, Claims 1-5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) *When claim text with markings is required.* All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn- currently amended."

(3) *When claim text in clean version is required.* The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, *i.e.*, without any markings in the presentation of text. The presentation of a clean version of any claim having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior

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version of the claims of the status of "withdrawn" or "previously presented." Any claim added by amendment must be indicated with the status of "new" and presented in clean version, *i.e.*, without any underlining.

(4) When claim text shall not be presented; canceling a claim.

- (i) No claim text shall be presented for any claim in the claim listing with the status of "canceled" or "not entered."
- (ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as "canceled" will constitute an instruction to cancel the claim.

(5) Reinstatement of previously canceled claim. A claim which was previously canceled may be reinstated only by adding the claim as a "new" claim with a new claim number.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a specific strain of *Dactylosporangium aurantiacum*. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It appears that a deposit was made in this application as filed as noted on page 9 of the specification. However, it is not clear if the deposit meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.

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2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.
5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5 are vague and confusing in the that parameters for tiacumicin production at the required levels are not recited with any particularity. Neither the microorganism to be used not the nutrient medium or culturing conditions are specified. Applicant fails to set forth the criteria that define a "the process of producing tiacumicin" other than providing a functional definition of "production" as "the yield of at least one tiacumicin is greater than about 50 mg/L fermentation broth..." Such functional language describes nothing about the biochemical, physical or structural properties of microorganism to be cultured or the culture medium to be used.

Attention is directed to *General Electric Company v. Wabash Appliance Corporation* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed.: "the vice of a functional claim exists not only when a claim is 'wholly' functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty".

Functional language at the point of novelty is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outline goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". Claims employing functional language at the point of novelty neither provide those element required to practice the invention, nor "inform the public during the life of the patent of the limits of the monopoly asserted.", *General Electric Co. v. Wabash Appliance Corp.*, at 468.

Claims 1-16 are vague, indefinite and confusing in the recitation of "is greater than about". The term "about" used to define the area of the lower end of a mold as between 25 to about 45% of the mold entrance was held to be clear, but flexible. Ex parte Eastwood, 163 USPQ 316 (Bd. App. 1968). Similarly, in *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), the court held that a limitation defining the stretch rate of

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a plastic as "exceeding about 10% per second" is definite because infringement could clearly be assessed through the use of a stopwatch.

However, the court held that claims reciting "at least about" (which is the same as "greater than about") were invalid for indefiniteness where there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term "about." *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991) (MPEP 2173.05(b))

Claims 7 and 8 are confusing in lacking clear antecedent basis in claim 1 for "said tiacumicin". Claim 1 is directed to "tiacumicins" or "at least one tiacumicin". It is unclear which is intended as written.

Claim 11 is vague, indefinite and confusing in the recitation "wherein the nutrient medium is fed with an additional carbon source as needed" To begin with, this phrase lacks antecedent basis in claim 1, where no carbon source is mentioned. In addition "as needed" is ambiguous and open to interpretation as to what constitutes "need" in this context.

Claims 15 and 16 are vague, indefinite and confusing in the recitation of trademarks to denote the adsorbents intended to be used in the process. The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name. "To describe physical or other properties of material by mere use of **trademark** is objectionable since it has tendency to make trademark descriptive of product rather than leaving trademark to serve its traditional purpose which is to identify product's source of origin". The issue involved the use of the Trademark **Hypalon** in the claims which Appellants have argued to be within the guidelines of M.P.E.P. 608.01 (v) if the meaning of the trademark is well known and satisfactorily defined in the literature. Copies of articles were submitted. No rejection was made based on first paragraph of 35 USC 112 which was correct but the rejection was on second paragraph which was considered to be correct by the board. "A patent applicant has an obligation that is imposed by 35 USC 112, second paragraph, to employ claim terminology

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which is definitive of what the public is not free to use, and use of a trademark in the manner employed by appellant has resulted in claims which fail to meet this obligation in our opinion.: see *Ex parte Simpson and Roberts* 218 USPQ 1020.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6, 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Hochlowski *et al.* (Tiacumicins, a novel complex of 18-membered macrolides. II. Isolation and structure determination. J. Antibiotics 40: 575-588, 1987)

The claims are directed to a process of producing tiacumicins by culturing a microorganism with a yield of tiacumicins greater than about 50 mg/l, 100 mg/l or 22 mg/l.

Hochlowski *et al.* disclose a process of producing tiacumicins by culturing a microorganism, *Dactylosporangium aurantiacum subspecies hamdenensis* NRRL 18085, with a yield of tiacumicins greater than about 50 mg/l, 100 mg/l or 22 mg/l. See, e.g., page 575, penultimate paragraph, line 9. See also indefiniteness rejection.

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Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hochlowski *et al.* taken with McAlpine *et al.*, Coronelli *et al.* (U.S. Patent No. 3978211), Waters *et al.* (U.S. Patent No. 4,632,902), Hoefle *et al.* (U.S. Patent No. 7,067,544) and Demain *et al.*

The claims are directed to a process of producing tiacumicins by culturing a microorganism with a yield of tiacumicins greater than about 50 mg/l.

Hochlowski *et al.* disclose a process of producing tiacumicins by culturing a microorganism with a yield of tiacumicins greater than about 50 mg/l under conventional culturing conditions. See, e.g., page 575, penultimate paragraph, line 9.

In addition, the production of various tiacumicin compound is disclosed by McAlpine *et al.* who teaches the production of tiacumicins with strain *Dactylosporangium aurantiacum subspecies hamdenensis* NRRL 18085 (See, e.g., Examples) and by Coronelli *et al.* (U.S. Patent No. 3978211) who teaches the production of lipiarmycins with *A. deccanensis*.

The invention as claimed differs from the references in the use of an adsorbent resin in the culture medium. However, each of Hoefle *et al.* and Waters *et al.* adequately demonstrates that it is old and well known in the art to add adsorbent resins, such as XAD-16 to culture media, for example, to isolate antibiotics produced by the strain or to isolate any antimicrobials present and thus prevent growth inhibition of the microorganisms cultured. See, e.g., Hoefle *et al.*, Example 3 and Waters *et al.*, bridging paragraph between col. 3 and 4 and col. 5.

The process conditions discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of process conditions, such as the sources of nutrients for the microorganism and the use of various adsorbents, including reverse silica gel, for optimization purposes identified as result-effective variables cited in the references would have been prima facie obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering. See, e.g., Demain *et al.* pages 123-126.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Hochlowski *et al.* of producing tiacumicins by adjusting the various ingredients of the culture medium, including the addition of an adsorbent thereto, as suggested by the teachings of Hoefle *et al.*, Waters *et al.* and Demain *et al.* for the expected benefit of maximizing the production of tiacumicin and of tiacumicin B, in particular, for treatment of infections with *Clostridium difficile*, for example.

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Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Irene Marx
Primary Examiner
Art Unit 1651